United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha. NE 68102

AUDIT REPORT FOR THE REPUBLIC OF IRELAND
APRIL 14 THROUGH MAY 2, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of the meat inspection system of the Republic of Ireland (hereinafter called Ireland) from April 14 through May 2, 2000. Six of the establishments certified to export meat to the United States were audited. Five of these were slaughter establishments, and one was conducting processing operations.

The last audit of the Irish meat inspection system was conducted in January-February 1999. Seven establishments were audited: five were acceptable and two were evaluated as acceptable/re-review. The following deficiencies were found at that time:

1. In Est. 293, no hot water was available for sanitizing in the slaughter area. *During this new audit, there was hot water, but it was not reliably maintained at the required temperature to sterilize contaminated knives and sharpening steels in three establishments (293, 344, and 355).*

2. Lighting was inadequate at the re-inspection station in Est. 293. *This had been corrected but, during the new audit, lighting was found to be inadequate at post-mortem inspection stations in all five slaughter establishments.*

3. Product ingredients in Est. 293 were not identified throughout the production process. *This had been corrected.*

4. In Est. 300, ventilation was not sufficient to reduce steam and odors in evisceration and inspection areas. *This had been satisfactorily addressed.*

In addition to the post-mortem lighting issue, the following new deficiencies were identified:

1. Hand-washing facilities were inadequate in two establishments (332 and 344), and workers were not washing their hands as required in two others (293 and 332).

2. Turnaround times in the residue testing laboratories did not meet FSIS requirements.

3. The intra-laboratory check sample programs in the residue testing laboratories did not meet FSIS requirements.

Importation of beef or beef products was not allowed at the time of this audit due to the presence of Bovine Spongiform Encephalopathy in Great Britain. The only restriction on pork products was that the product must be indigenous and processed in a dedicated establishment that receives no animals from countries where Swine Vesicular Disease exists (these conditions were fulfilled in Ireland).

In 1999, four establishments (293, 332, 355, and 356) exported 7,170,124 pounds of pork and pork products to the U.S., of which 2% was rejected at ports of entry (POE): 1.1% for processing defects, 0.6% for contamination (Est. 356), 0.3% for unsound condition, 0.07% for missing shipping marks, and 0.02% for transportation damage. During the first 2 months of 2000, the same 4 establishments exported 1,324,920 pounds: 0.57% was rejected at POE for missing shipping marks.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Irish national meat inspection officials to discuss oversight programs and practices, including enforce-ment activities. The second entailed an audit of a selection of records in the meat inspec-tion headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments. The fourth was a visit to three laboratories, two performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmon-ella*.

Ireland's program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the FSIS auditor (hereinafter called "the auditor") evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials (this was the case with two establishments—see below).

RESULTS AND DISCUSSION

Summary

Based on the performance of the individual establishments, Ireland's "In-Plant Inspection System Performance," as a whole, was evaluated as In-Plant System Controls In Place.

Effective inspection system controls were found to be in place in four of the six establishments audited; three of these (Ests. 300, 344, and 355) were acceptable and one (Est. 332) was recommended for re-review. Two establishments (293 and 552) were found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli,* are discussed later in this report.

Entrance Meeting

On the morning of April 14, an entrance meeting was held in the Dublin offices of the Department of Agriculture, Food, and Rural Development (DAFRD), and was attended by Mr. Paddy Rogan, Deputy Chief Veterinary Officer; Mr. Michael Dillon, Higher Exec-utive Officer (Meat Trade Division, Agriculture House); Mr. Pat Branagan, Superintend-ing Veterinary Inspector (Special Investigation Unit, Agriculture House); Mr. Frank Kenny, Senior Superintending Veterinary Inspector (Agriculture House); Mr. Canice Bennet, Superintending Veterinary Inspector (Agriculture House); Mr. Ted Duffy, Superintending Veterinary Inspector (East Region, Regional Officer); Mr. Cecil Alexander, Superintending Veterinary Inspector (Central Meat Control Laboratory); Mr. Michael Hanley, Agricultural Attaché, American Embassy; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The topics of discussion included the following:

1. The audit itinerary and lodging accommodations were finalized.

2. The auditor provided a copy of the current Enforcement Quarterly Report and in-formed the DAFRD officials where it could be located on the FSIS home page. He inquired whether Ireland also makes similar information available to the public; the Irish officials replied that the results of the Government of Ireland's (GOI) enforce-ment activities were not generally made available to the public at the time, and that there were no specific plans to do so in the foreseeable future, but the information was available through Ireland's Freedom of Information Act.

3. The auditor provided copies of the data-collection instruments he would be using in the audits of the individual establishments (Attachments A, B, C, and D).

4. Information was provided to update the FSIS country profile for Ireland.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Ireland's inspection system.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The auditor observed and evaluated the process.

The auditor conducted a review of inspection system documents in general, and also of documents pertaining to the establishment (356) that was not visited on-site, at the headquarters of the inspection service. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Sampling and laboratory analyses for residues.
- Notices informing field personnel of new Pathogen Reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of non-compliance records and the related forms used in case of further non-compliance, records of criminal prosecution, and seizure and control of noncompliant product.
- For Est. 356, copies of the HACCP plan, the SSOP program, the written programs and records for testing for *Salmonella* and *E. coli*, and monthly supervisory review reports.

No concerns arose as a result the examination of these documents.

Government Oversight

All ante- and post-mortem inspection veterinarians and inspectors in establishments certified by Ireland as eligible to export meat products to the United States were DAFRD employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Seven establishments were certified to export meat and/or poultry products to the United States at the time this audit was conducted; six were visited for on-site audits. In four of the six establishments visited, both DAFRD inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adultera-tion of products.

Laboratory Audits

During the three laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The Central Meat Control Laboratory in Dublin was audited on April 28, 2000. Except as noted below, effective controls were in place for sample handling and frequency, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done. The following deficiencies were identified:

1. Most turnaround times (the amount of time between sample reception in the laboratory until analysis is complete) did not meet the FSIS requirement of ten working days. The turnaround times for routine field samples in this laboratory were: for routine antibiotics 6 weeks, for chloramphenicol up to 5 weeks, for tetracyclines up to 9 months, for diethylstilbestrol (DES) 3-4 months, for sulfonamides up to 4 months, for carbadox 2 months, and for ivermectin 6 months. Note: analyses for antibiotics from suspect animals were completed within 24 hours of reception.

2. The intra-laboratory check sample (CS) program did not meet FSIS standards, which require that each analyst must participate in a CS program, at least once per calendar month, for each class of substances for which he/she performs the field analyses for the national residue testing program. There had not been a quality manager in this laboratory for more than a year, since the previous one had accepted a new job offer and had not been replaced. Check samples for antibiotics were being done every 3 months. No check samples for chloramphenicol had been done for some two years: the person in charge of this section stated that there was "not enough time." The last CS for tetracyclines was done in October 1999, and for DES on 9/24/99 (due to failure of a spectrophotometer—a new one had been ordered), for sulfas August 1998 (the section supervisor stated that no extra CS program was necessary for sulfas, since each kit came with its own controls). Check samples for carbadox, ivermectin, and sedatives were being run together with field samples, which were being held for up to 3-6 months so that several could be run at the same time.

3. There was no written program for corrective actions in the event that an analyst's proficiency did not meet expectations. As stated above, there had not been a quality manager in this laboratory for more than a year.

4. No formal standards books were maintained in the section for chloramphenicol and DES. The supervisor stated that he "[goes] by experience." Expiration dates of analytes were not tracked. No record was being kept of the dates of preparation for the standard solutions.

5. The standards book for carbadox and ivermectin did not contain the source of the analytes, lot numbers, or expiration dates.

NOTE: This laboratory was owned and operated by the Department of Agriculture, Food, and Rural Development (DAFRD), but it had not been accredited. DAFRD officials had submitted a "draft work plan" with a request for additional resources to establish qualification for accreditation. Attempts by the DAFRD staff involved with the laboratory to improve the situation had been made, and the auditor was informed that the process must be approved by numerous levels of the government administration. The same official stated that an independent study of the laboratory's operations had determined that twenty additional staff were needed.

The Pesticide Control Service Laboratory in Dublin was also audited on April 28, 2000. Except as noted below, effective controls were in place for sample handling and frequen-cy, data reporting, tissue matrices for analysis, equipment operation and printouts, mini-mum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done. The following deviations from FSIS requirements were identified:

1. Turnaround times (the amount of time from reception in the laboratory until the analyses are complete) for all compounds was approximately two months. FSIS expects turnaround times of ten working days.

2. Check samples were being run together with each batch of field samples (approx-imately every two months). FSIS standards require that each analyst must participate in a check sample program, at least once per calendar month, for each class of sub-stances for which he/she performs the field analyses for the national residue testing program.

Ireland's microbiological testing for *Salmonella* was being performed in a private labor-atory, the Independent Micro Lab, Ltd.; it was audited on April 27. The auditor deter-mined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratory has been accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratory has properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

<u>Establishment Operations by Establishment Number</u>

The following operations were being conducted in the six establishments audited:

Beef cutting and boning – 1 establishment (552)
Beef slaughter and boning – 1 establishment (344)
Beef slaughter, boning, and cutting – 1 establishment (300)
Pork slaughter, boning, cutting, and curing – 2 establishments (332, 355)
Pork slaughter, boning, curing, smoking (not for U.S.), and raw sausages – 1 establishment (293)

SANITATION CONTROLS

Based on the on-site audits of establishments, Ireland's inspection system had controls in place for water potability, chlorination procedures, back-siphonage prevention, separation of establishments, pest control programs and monitoring, work space, dry storage areas, ante-mortem and welfare facilities, outside premises, and personal dress and habits.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements in Ests. 300, 332, 344, and 355. The following deficiencies were found in the other two premises:

1. In Est. 293, documentation by the establishment of operational and pre-operational findings, corrective actions, and preventive measures did not reflect the conditions observed during the audit. There was no documentation by the establishment of identification of condensation problems, corrective actions, or preventive measures in response to condensation problems (severe condensation problems were encountered during the audit).

2. In Est. 552, operational sanitation activities were not adequately addressed in the written SSOPs. Documentation of pre-operational sanitation findings, corrective actions, and preventive measures was inadequate.

Cross-Contamination

1. No hand soap was available at any of the post-mortem inspection stations in Est. 332, or at either the final carcass inspection station or at the pre-boning trim station in Est. 344. New dispensers were to be installed promptly.

2. Sanitizers with inadequate temperatures were found in Ests. 293, 344, and 355. Corrective actions were taken, but this was a repeat finding in Est. 293.

3. Product-contact surfaces had not been adequately cleaned before the start of production and the establishment personnel failed to recognize the problem during pre-operational sanitation inspection in Ests. 332 and 552. Improvements were ordered by DAFRD.

Product Handling and Storage

Condensation was out of control in Est. 293, and attempts at corrective action were both ineffective and not carried out in a timely manner. Condensation was not adequately controlled in Est. 552, and the audit team vacated the area before corrective actions were observed.

Personnel Hygiene and Practices

Workers were observed to fail to wash their hands before entering production areas in Ests. 293 and 332. Corrective actions were immediate.

Basic Establishment Facilities

1. FSIS requires 50 foot-candles (fc) of shadow-free light at the inspection surfaces. Light at post-mortem inspection stations was found to be inadequate in Establishments 293 and 332. Furthermore, although the light intensity was actually sufficient with no product present in Ests. 300, 344, and 355, the light at the inspection surfaces of the medial retropharyngeal lymph nodes was inadequate (in Est. 355, light in abdominal cavities was also insufficient). In all cases, management personnel expressed willingness to upgrade the lighting to meet the requirements.

2. Deteriorated product-contact equipment in need of repair or replacement was found to be in use in Ests. 293 and 552. Improved programs were ordered by DAFRD.

3. Neglected maintenance and cleaning of over-product structures was seen in Ests. 293, 332, and 355 and to a lesser extent, in Est. 300. DAFRD ordered improved programs.

ANIMAL DISEASE CONTROLS

Ireland's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There was no mention of outbreaks of animal diseases with public-health significance since the previous U.S. audit.

In addition to the national residue testing program, Ireland had developed a "Plant's-Own Self-Monitoring Program," under which each export establishment tested 0.5% (beef) / 1% (swine) of the volume slaughtered in that establishment during calendar year 2000.

Violations resulted in 25% of the subsequent stock from that supplier being sampled. If there were any further positives, 100% of that supplier's stock were sampled. In addition, any DAFRD veterinarian had the full authority to take samples from any animal.

To address the demand for the creation of a central data base that would contain comprehensive details of the origin, identity, and location of cattle, Council Regulation 820/97 established a common European Union (EU) framework of rules for bovine animal identification and tracing and labeling of beef. The EU rules identified four "pillars of identification:" ear tags, identity cards, on-farm herd registers, and computerized data bases containing full information on animal identity and location. At the same time, at the Irish national level, a "National Beef Assurance Scheme" (NBAS) was established, that ensures a comprehensive traceability system for Irish cattle. This system was demon-strated for the auditor.

A Clean Livestock Policy has also been in effect in Ireland since 1998: animals had been divided into 5 categories of cleanliness; excessively-soiled animals were rejected for slaughter. This program had been added to ante-mortem inspection legislation.

RESIDUE CONTROLS

Ireland's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Irish inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Irish inspection system had controls in place to ensure adequate humane handling and slaughter, ingredients identification, control of restricted ingredients, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing records, post-processing handling, and processing defect actions by establishment personnel, and processing control by inspection personnel.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system.

Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements, with the exception that, in Est. 552, the establishment's documentation of monitoring of in-coming product did not reflect the actual conditions observed either by the FSIS auditor on the day of the audit nor by the inspection officials during their recent verification of the establishment's monitoring of critical limits. The establishment records revealed not a single instance of contamination during the month of March 2000, whereas the inspection service's monitoring documented many instances of fecal and other contamination. One of the two critical control points was the absence of contamination on incoming product.

Testing for Generic *E. coli*

Ireland had adopted the FSIS regulatory requirements for *E. coli* testing. Five of the six establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accom-panies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent meat products intended for Irish domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the DAFRD inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documenta-tion of corrective actions under HACCP plans), inspection supervision and documenta-tion, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat products from other counties for further processing] were in place and effective in ensuring that products produced by the establishments were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

No formal, documented boneless meat reinspection was being carried out in Ests. 300 and 552. In Est. 344, boneless meat was reinspected, but the results were not documented. Forms were available at DAFRD headquarters; a program was to be developed and implemented promptly. The boneless meat reinspection criteria sheet in use in Ireland had not been updated to reflect the zero-tolerance policy that requires all contamination with fecal material or ingesta to be classified as a critical defect. Note: a review of the documents created since 1/1/00 revealed no instance of contamination with feces or ingesta. The FSIS requirements for boneless meat reinspection and documentation were discussed in the establishments and in the country exit meeting; DAFRD officials agreed to ensure the development of compliant programs and to update the reinspection criteria sheets.

Testing for *Salmonella* Species

Five of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Ireland had adopted the FSIS regulatory requirements for *Salmonella* testing with exception of the following equivalent measures:

1. Program development: establishments certified to export meat to the United States develop their own *Salmonella* testing program and the program is approved by Ireland.

2. Sample collection: establishment personnel collect the samples, and Ireland provides oversight and monitoring of the establishment's sampling procedures,

3. Laboratories: Ireland uses a private laboratory for *Salmonella* testing, which:
   - has been accredited by Ireland,
   - has suitable facilities and equipment, properly trained personnel, reporting and record-keeping capabilities, and a written quality assurance program, and
   - reports test results directly to the government of Ireland.

The auditor verified that Ireland had adopted the FSIS regulatory requirements for *Salmonella* testing as stated above, and that the *Salmonella* testing programs, as implemented in the establishments, were found to meet the basic FSIS regulatory requirements.

Ireland had adopted the FSIS performance standards for *Salmonella*. There had been no performance standard failures in swine. There had been no positive samples at all in beef. If performance standards were exceeded, the actions specified in the USDA rule would apply: at the first failure, measures would be taken to correct the problem, at the second, a review of the HACCP system would be undertaken and, at the third, inspection would be withdrawn. All levels of DAFRD would be involved in these actions.

Samples for *Salmonella* testing were delivered to the private lab the same day they were taken, and were analyzed the same day they were received. Results were reported to both establishment and DAFRD officials independently. The owner or operator is legally required, under Irish law, to report to the Minister of Agriculture any result that can have negative public health effects. In 1999, an establishment (not USDA-certified) was suspended for failure to report such a result.

Species Verification Testing

At the time of this audit, Ireland was exempt from the species verification testing requirement, having advised FSIS in writing that the following five conditions were being met:

1. Carcasses and products are transported between establishments in devices which are sealed with a tamper-detectable inspection seal by the Inspection Service at the originating establishment and broken by the Inspection Service at the receiving establishment.
2. Brands and sealing devices used by the Inspection Service to identify and seal product are kept under Inspection Service security.
3. Establishments are under continuous Inspection Service supervision while operating. No operations may take place without Inspection Service supervision.
4. Only one species of livestock or meat is allowed in the slaughter or processing areas at one time.
5. Product must be exported to the United States in a cargo container sealed by the Inspection Service.

During the audit, the auditor verified that these conditions continued to be met. With regard to the fifth condition, the seals applied by the inspection service were supplied by the establishment of origin, and not issued by the inspection service.

Monthly Reviews

FSIS requires monthly supervisory visits to U.S.-listed establishments during any month when they are producing U.S.-eligible product. These reviews were being performed by six Regional Veterinary Officers, who headed the six Public Health Regions. They performed the initial periodic reviews, and reported directly to Dr. Paddy Rogan. There was also a headquarters level of review, headed by Dr. Frank Kenny. All the internal reviewers were veterinarians with at least five years of experience in meat inspection, and had full authority up to and including delistment of the establishment. The schedule of the internal reviews was arranged by the Regional Veterinary Officers, each of whom developed the program in his region and determined the establishment selection on the basis of compliance, performance, and the findings of headquarters reviews.

The internal review program was not applied equally to both export and non-export establishments; however, all abattoirs were subject to daily veterinary inspection by local authorities. Both regional and headquarters reviews were usually unannounced, but occasionally were announced (48 hours maximum advance notice for regional; 4-5 days for headquarters reviews), and were usually conducted by a team of at least two reviewers, at least once monthly. The records of audited establishments were kept by the individual auditors; some were also available in the inspection offices of the individual establishments, but not all. Copies were routinely maintained on file for at least three years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, the inspection report is examined in detail, then a corrective action program is formulated and, and announced and unannounced visits are paid by regional and headquarters reviewers, whose reports must be favorable for the establishment to be considered for reinstatement.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Ireland's internal review program as a whole.

Enforcement Activities

Irish meat inspection authorities demonstrated a well-developed enforcement program. A deficiency noted by inspection personnel was recorded on a Noncompliance and Correct-ive Action Report. Further noncompliance triggered the generation of a Notice under Regulation 12 (6) – Fault Identification/Correction, usually called a "Twelve-Six," a legally binding document requiring the establishment to correct a deficiency within the time period specified by the inspection official in the document. In the event that this does not achieve the expected results, or in case of a noncompliance that indicates a public health risk, a Notice under Regulation 12. (7), or "Twelve-Seven" would be issued, which requires the "person in charge of the plant:

(a) to reduce the rate of throughput to a level consistent with acceptable hygiene standards, or
(b) to temporarily suspend the use of the equipment [identified], or

(c) to temporarily suspend the use of the [specified] plant areas for the preparation, handling, packaging, storage or loading of fresh meat, or
(d) to temporarily suspend the production activity [specified] pending the elimination of the identified defects."

The inspection official issuing this document would strike through the non-applicable measures. The auditor observed the issuance of all three of the above documents during the course of the audits of the establishments.

The Irish officials also provided summaries of the following enforcement activities:

1. A summary of the prosecution and sentencing of three persons for (1) possession of meat not bearing a health mark, (2) supply of meat not bearing a health mark, and (3) application of a health mark to meat by a person not authorized to do so;

2. The chronology of an investigation for a positive *Listeria monocytoges* finding in a routine sample of a cooked poultry meat product; and

3. A summary of an investigation of an instance of failure of the management of an establishment to notify the Minister of Agriculture, as required by Irish legislation, of any information pertaining to serious food safety risks associated with its products. In this case, the risk involved the finding of *Salmonella* species in a food product. The establishment's operations were suspended by DAFRD.

Exit Meeting

An exit meeting was conducted in Dublin on May 2. The participants were Mr. Paddy Rogan, Deputy Chief Veterinary Officer; Mr. Michael Dillon, Higher Executive Officer (Meat Trade Division, Agriculture House); Mr. John Bracken, Assistant Principal Veterinary Officer; Ms. Catherine Murray, Clinical Officer; Mr. Martin O'Sullivan, Senior Superintending Veterinary Inspector; Drs. Canice Bennett and James Egan, Superintending Veterinary Inspectors; Mr. Michael Hanley, Agricultural Attaché, American Embassy, Dublin; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The following topics were discussed:

1. Information to complete the country audit profile, requested during the entrance meeting, was provided, and included statistics on recent incidents of food-borne illness and a summary of the training program for veterinary inspectors in export-approved premises.

2. Copies of the delistment notices for the two unacceptable establishments (293 and 552) were provided.

3. The audit findings, with special emphasis on the deficiencies identified, were discussed.

4. The FSIS requirements for boneless meat reinspection and documentation, as well as documentation of the zero-tolerance policy for ingesta were discussed; DAFRD officials

agreed to ensure the development of compliant programs and to update the reinspection criteria sheets.

CONCLUSION

The inspection system of Ireland was found, on the whole, to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments.

Six establishments were audited: three were acceptable, one was evaluated as accept-able/re-review, and two were determined by the Irish supervising meat inspection officials to fail to meet FSIS requirements and were therefore found unacceptable, and each was removed by them from the list of establishments eligible to export meat products to the United States, as of the start of operations on the day of its audit. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. Gary D. Bolstad (signed)Dr. Gary D. Bolstad
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* testing
E. Laboratory audit form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)
H. FSIS Response(s) to Foreign Country Comments (when it becomes available)

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
293	√	√	INAD.	√	√	√	NO	√
300	√	√	√	√	√	√	√	√
332	√	√	√	√	√	√	√	√
344	√	√	√	√	√	√	√	√
355	√	√	√	√	√	√	√	√
552	√	√	INAD.	√	√	√	INAD.	√

293: Operational sanitation was documented, but documentation did not reflect conditions observed. Condensation was out of control; there was no documentation by the establishment. Condensation control not addressed in op-san-SSOPs.

Documentation was also audited from the following establishment that was not visited on-site, during the centralized document audit:

356	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. 12, which was a cold-storage facility) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
293	√	√	√	√	√	√	√	√	√	√	√	√
300	√	√	√	√	√	√	√	√	√	√	√	√
332	√	√	√	√	√	√	√	√	√	√	√	√
344	√	√	√	√	√	√	√	√	√	√	√	√
355	√	√	√	√	√	√	√	√	√	√	√	√
552	√	√	√	√	√	√	√	√	√	√	NO	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

356	√	√	√	√	√	√	√	√	√	√	√	√

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment (except Est. 552, which was not a slaughter facility) was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
293	√	√	no	√	√	√	√*	√	√	√
300	√	√	√	√	√	√	√	√	√	√
332	√	√	√	√	√	√	√	√	√	√
344	√	√	√	√	√	√	√	√	√	√
355	√	√	√	√	√	√	√	√	√	√
552	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

293: If the randomly selected carcass was inaccessible, a new random number was chosen, and so on, until a more easily reached carcass was selected. (The carcass coolers were very full and congested.)

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

356	√	√	√	√	√	√	√	√	√	√

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is/are being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
293	√	√	√	√	√	N/A
300	√	√	N/A	√	√	N/A
332	√	√	N/A	√	√	N/A
344	√	√	√	√	√	N/A
355	√	√	√	√	√	N/A
552	N/A	N/A	N/A	N/A	N/A	N/A

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

356	√	√	√	√	√	√